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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,969	09/25/2000	Johannes M. Van Noort	101137-4	3142

7590

11/28/2001

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EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

¹⁶⁴⁴
Remained 1-8-02
DATE MAILED: 11/28/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/668,969

Applicant(s)

Van Noort et al.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/975696.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

DETAILED ACTION

1. Claims 1-4 are under consideration.

Specification

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821-1.825, however, this application fails to comply with the requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

This application discloses sequences for which no sequence listing has been submitted. However, a sequence listing including said sequences was submitted in parent application 08/975696.

Therefore, the following procedure can be used because this application contains the same sequence disclosure as the parent. The applicant need not submit a new computer readable form of the Sequence Listing for this divisional application. However, (1) the specification must contain a paper copy of the new Sequence Listing containing the aforementioned sequence, (2) applicant must request in writing that the CRF in the parent case be used to prepare a file for the offspring and (3) applicant must submit a statement that the paper copy of the Sequence Listing in the offspring is identical to the computer readable form submitted in the parent case.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. The specification fails to provide guidance as to how to make or use the claimed composition or "at least a specific immunogenic part thereof" in a method of therapeutic treatment. Although the amino acid sequence of alpha B crystallin is disclosed in the specification (see Figure 3, of the specification, in particular), there is no evidence of record to show that one skilled in the art would associate the said sequence or "at least a specific immunogenic part thereof" with the successful therapeutic treatment claimed herein. Applicant has provided no examples using alpha B crystallin or an immunogenic part of alpha B crystallin to treat disease in humans or any animal model. Besides the identification of alpha B crystallin in myelin from patients with multiple sclerosis, which was previously taught by Iwaki, et al., ((W) see page 346, Table 1, in particular), and Murayama, et al. ((X) see page 32, col. 2, paragraph 2, in particular), the specification fails to provide guidance as to how to use the claimed alpha B crystallin or immunogenic parts thereof, for therapy of autoimmune disorders or for patients with multiple sclerosis. Typically, an autoimmune disease is diagnosed at the time of onset when significant tissue damage has already occurred. Furthermore, Tisch et al., teach that treating an ongoing T-cell-mediated autoimmunity by administering an antigen peptide may have an immunizing effect and exacerbate the disease condition (page 437, column 3, in particular). How the antigen is administered is also a key factor in determining whether an immunogenic or toleragenic response is induced. The duration of the toleragenic effect is an additional factor. Frequent treatment over a prolonged period of time may result in unforeseen immunological complications. Additionally, the high degree of specificity required for the process of clonal deletion/anergy may be limiting when dealing with diseases such as MS, in which there are responses to several antigens (see page 437, col. 2 ¶ 3 and bridging over to col. 3, ¶ 4). Wraith et al. teach the "Inhibition of the response restricted by one class II molecule may lead only to the escape to an autoimmune response to a separate epitope restricted by a different class II molecule." (see page 253 column 1, in particular). Therefore, since the applicant has given no guidance as to how their peptide specific therapy would overcome autoreactive T cell escape mechanisms in humans or whether the peptide would induce autoimmunity or tolerance, and because there is no evidence of record to show that one skilled in the art would associate the said detection of alpha B crystallin in myelin from patients with multiple sclerosis with the successful therapeutic treatment claimed herein, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention and this is not sanctioned by the statute. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --
(f) he did not himself invent the subject matter sought to be patented.
6. Claims 1-4 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.
Van Noort et al. (WO 95/33997) teaches the claimed invention (see claims).
Therefore, Van Noort et al. (WO 95/33997) establishes that the claimed invention was not invented by applicant (eg. WO 95/33997 has three inventors whilst the instant application has two).
7. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.
8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is (703)308-4680. The Examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800-1622

November 27, 2001
Ron Schwadron, Ph.D.
Primary Examiner
Group 1640